Remarks

Applicants request reconsideration on the merits of the above-referenced patent application.

I. Amendments to specification

The amendments to the specification are shown on pages 2-8. Applicants submit that none of the amendments introduce new matter. More specifically:

In accordance with MPEP §201.11(III), a new section has been inserted at the beginning of the specification reciting the priority claim. This priority claim was recited in the text that Applicants' December 8, 2005 Preliminary Amendment requested to be inserted at line 1 on page 1. The new text above, however, further elaborates on the priority claims of the parent and grandparent priority documents.

Other amendments simply rephrase the specification, or correct grammatical or obvious errors. Applicants submit that such amendments are permissible under MPEP §2163.07.

II. Claim Amendments

Claims 6-11 are pending, and have been amended by this amendment. Applicants submit that the amendments do not introduce new matter. Specifically:

Claims 6, 7, 9, and 11 have been amended to remove the characterization of the vaccine bacteria as being "attenuated". Thus, the claims now encompass the use of all live strains rather than being specifically limited to those characterized as being attenuated. This amendment is supported by Applicants' specification at, for example, page 1, lines 20-21. This amendment also is supported by Examples 1-3 on pages 7-9, which illustrate the use of four different live bacterial strains, including both attenuated and virulent strains.

Other amendments rephrase the claims (*e.g.*, make the claim language more consistent) or correct grammatical or obvious errors. Applicants submit that such amendments are permissible under MPEP §2163.07.

Applicants reserve the right to pursue any canceled subject matter and/or any other subject matter disclosed in this application in one or more divisional and/or continuation applications.

III. Double patenting rejections

Claims 6-11 have been rejected under the judicially-created doctrine of obviousness-type double patenting in view of claims 1-4 of U.S. Patent No. 6,682,745. Applicants submit that this rejection is premature because claims 6-11 have not yet been found to be otherwise allowable. Applicants will file a terminal disclaimer (to the extent necessary) once the claims in this application have been found to be otherwise allowable.

Claims 6-8 have been rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,120,775. Applicants submit that this rejection is premature because claims 6-8 have not yet been found to be otherwise allowable. Applicants will file a terminal disclaimer (to the extent necessary) once the claims in this application have been found to be otherwise allowable.

IV. Written description rejection

Claims 6-11 have been rejected under 35 U.S.C. 112 (first paragraph) for lacking written description. Specifically, these claims have been rejected for lacking written description as to the term "attenuated". Applicants request reconsideration of this rejection.

Applicants' invention stems from their discovery that submucosal administration of live vaccines generally tends to reduce local reactions that had previously been observed when live vaccines were administered via the conventional routes for systemic application (particularly intramuscular administration). This reduction of local reactions allows for less-attenuated vaccines to be used. *See, e.g.*, Applicants' specification, page 1, lines 20-24.

Prior to the above amendments, Applicants' claims were directed to use of live attenuated vaccines. Applicants submit that their specification provides sufficient written description for the term "attenuated." This is particularly true when their specification is viewed in combination with the knowledge that existed in the art at the time of their earliest

priority filing. That knowledge, for example, included various publicly available live attenuated vaccines. Although Applicants' Example 1 focuses on *S. equi* strains, any of the publicly available strains could also have generally been used. Applicants, in fact, note this in their specification. *See, e.g.*, page 1, lines 25-28. Applicants should not be penalized for omitting specific descriptions of such vaccines and their preparation. After all, as noted in MPEP §2164.01, a patent "preferably omits" anything that is already well known in the art.

Despite the foregoing, in an effort to expedite prosecution of this patent application, the claims have been amended to remove the term "attenuated." Thus, claims 6-8 are now directed to a method for administering a live vaccine, and claims 9-11 are now directed to a method for reducing the amount of adverse reactions at an injection site of a live bacterial vaccine. This scope is supported by the written description in Applicants' specification. For example, all three of Applicants' examples on pages 7-9 support this scope by illustrating the invention using both attenuated and virulent strains of bacteria in vaccines. These examples not only demonstrate the advantages of this invention using **four** different bacterial strains, but also demonstrate the advantages of this invention using **two** different mammalian host species.

Applicants also submit that their claims comply with the precedent set forth in the Federal Circuit's recent decision, Capon v. Eshhar, 76 USPQ2d 1078 (Fed. Cir. 2005). In that case, the Court held that 35 U.S.C. §112 (first paragraph) does not *per se* prohibit open claiming of nucleotide sequences where the invention relates to a novel combination of known DNA segments to achieve a novel result rather than to the DNA sequences themselves. See Capon, pages 1084-85. Analogous to the claims in Capon, Applicants' claims are directed to the use of live vaccines (including known live vaccines) to achieve a novel result (*i.e.*, reduced local reactions) rather than to the live vaccines themselves. Thus, under the precedent set forth in Capon, Applicants submit that they have properly claimed their methods. See also, Example 8 on page 26 of the Revised Interim Written Description Guidelines Training Materials, http://www.uspto.gov/web/patents/guides.htm (finding the written description requirement to be satisfied where, *inter alia*, "any substantial variability within the genus arises due to addition of elements that are not part of the inventors' particular contribution"). This is particularly true, given the fact that Applicants' specification provides

over two pages identifying bacteria that are generally suitable for use with their invention, as well as three working examples that corroborate their invention using multiple live bacterial strains and multiple mammalian host species. See, e.g., page 3, line 25 to page 5, line 29; and pages 7-9.

Simply put, the claims recite Applicants' contribution, *i.e.*, an administration route for live bacterial vaccines that generally reduces the adverse reactions that were previously observed with conventional routes of administration. The variability within the claims (*i.e.*, the live bacteria used) arises from aspects that are not part of Applicants' particular contribution. Applicants' specification provides instruction as to this breadth. Moreover, various vaccines suitable for this invention (*i.e.*, live vaccines) were publicly known and available at the time of Applicants' invention. Thus, requiring Applicants to further narrow the claims to specific live vaccines would unnecessarily and arbitrarily limit the claims to less than Applicants' complete invention. Applicants submit that this rejection should therefore be withdrawn.

V. Enablement rejection

Claims 6-11 have been rejected under 35 U.S.C. 112 (first paragraph) for lacking enablement. Specifically, these claims have been rejected for lacking enablement as to the term "attenuated". Applicants request reconsideration of this rejection.

As noted above, the term "attenuated" has been removed from the claims, thus mooting the concerns in the rejection. Claims 6-8 are now directed to a method for administering a live vaccine, and claims 9-11 are now directed to a method for reducing the amount of adverse reactions at an injection site of a live bacterial vaccine. Applicants' specification enables the full scope of the claims. Applicants' specification, for example, provides generally suitable sites for submucosal administration at, for example, page 2, line 30 to page 3, line 2 and page 3, lines 18-23; administration depths and techniques at, for example, page 3, lines 3-17; dosage ranges at, for example, page 6, lines 1-8; suitable carrier materials at, for example, page 6, lines 9-17; suitable adjuvants at, for example, page 6, lines 18-26; and three working examples illustrating the invention using four bacterial strains and

two mammalian host species at pages 7-9. Applicants' specification also, for example, identifies various live bacteria that are generally suitable for use with their invention at, for example, page 3, line 25 to page 5, line 29. In view of the foregoing support, Applicants submit that the claims are enabled.

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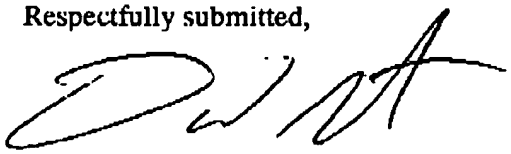
Applicants hereby request a two-month extension to respond to the June 28, 2005 Office action, and authorizes the Commissioner to charge Deposit Account No. **02-2334** for the corresponding extension fee. Applicants do not believe that any other fee is due in connection with this filing. If, however, Applicants do owe any such fee(s), the Commissioner is hereby authorized to charge the fee(s) to Deposit Account No. **02-2334**. In addition, if there is ever any other fee deficiency or overpayment under 37 C.F.R. §1.16 or 1.17 in connection with this patent application, the Commissioner is hereby authorized to charge such deficiency or overpayment to Deposit Account No. **02-2334**.

Applicants submit that the pending claims are in condition for allowance, and request that this application be allowed. The Examiner is requested to call the Undersigned if any issues arise that can be addressed over the phone to expedite examination of this application.

Respectfully submitted,



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